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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,334	03/07/2007	Francesco Santangelo	U 016325-6	9753

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
10/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

Office Action Summary	Application No.	Applicant(s)	
	10/583,334	SANTANGELO, FRANCESCO	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's Request for Continued Examination (RCE) filed September 29, 2006 is acknowledged and accepted. Claims 1, 2 and 4 are canceled. Accordingly, claims 3 and 10 remain under consideration.

A Declaration filed March 31, 2009 by Francesco Santangelo is further acknowledged.

Objections and rejections set forth in previous Office Actions that are not herein reiterated are withdrawn. The following rejections constitute the only rejections presently applied to the instant claims.

Applicant is again requested to send a complete list of his co-pending and related applications drawn to the administration of cystine and/or cysteine.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3 and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,627,659. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are drawn to decreasing the effect of oxidative stress in a patient undergoing hemodialysis comprising administering N-acetylcysteine. Using the instant specification as a dictionary, N-acetylcysteine is defined as a prodrug. See page 3 of the specification, line 5. Accordingly, N-acetylcysteine is an inactive substance that undergoes chemical conversion *in vivo* to cysteine, the active metabolite.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Locatelli et al., Nephrology, Dialysis, Transplantation, in view of Droge et al., U.S. Patent 5,607,974.

Locatelli teaches the administration of N-acetyl cysteine to treat oxidative stress resulting from hemodialysis in a patient undergoing hemodialysis. See, in particular, the second column on page 1274 under **Oxidative Stress**, where Locatelli teaches

hemodialysis induces oxidative stress. A direct increase in blood levels of reactive oxygen species is noted during hemodialysis. The duration of hemodialysis is also a factor in determining oxidative stress in this patient population. See the Abstract where N-acetyl cysteine is disclosed to be a suitable antioxidant to treat oxidative stress.

The claims differ in that Locatelli teaches the administration of N-acetyl cysteine, not cysteine, and Locatelli fails to teach oral administration. However, N-acetylcysteine is defined by Applicant as a prodrug. See page 3 of the specification, line 5. Accordingly, N-acetylcysteine is an inactive substance that undergoes chemical conversion *in vivo* to cysteine, the active metabolite.

Further, Droge teaches the oral administration of cysteine to patients receiving hemodialysis. See column 2, lines 14 and 66, as well as column 3, lines 14-19, where the cysteine dosage range is taught to be 200mg to 2 gm.

Therefore, in view of the combined teachings of Locatelli and Droge, one skilled in the nephrology art would have been motivated to administer cysteine to treat oxidative stress that results from hemodialysis. Such would have been obvious because, for a patient undergoing hemodialysis, cysteine, the active metabolite of N-acetyl cysteine *in vivo*, acts as a scavenger of oxygen free radicals and is therefore effective in reducing oxidative stress.

No claim is allowed.

Zaloga et al., U.S. Patent 6,060,446, is cited to show further the state of the art with respect to the utility of cysteine to act as a scavenger of oxygen free radicals and to reduce cellular injury.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 23, 2009

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614